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EXAMINER

YABUT, DIANE D

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This action is in response to applicant's amendment received 11/05/2007.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 6-7, 25, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Epstein** (U.S. Patent No. **6,045,570**) in view of **Belef** (U.S. Pub. No. **2002/0193808**).

Claims 1, 6-7, 25, 28-30: Epstein discloses a tubular or outer member **111** having a proximal end, a distal end sized for insertion into a puncture, and a lumen extending between the proximal and distal ends, an elongate occlusion member or inner member **33** slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member, an expandable member **32** on the occlusion member distal end, a delivery device **81** coupled to the proximal end of the tubular member, the delivery device comprising a plunger **86** that is advanceable to deliver a sealing compound into the tubular member lumen. The tubular member is retracted proximally relative to several telescoping tubular members (elongate member, sheath) before the sealing compound is delivered to at least partially fill the puncture (Figure 1, 5A-5C).

Epstein does not expressly disclose a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member which is biased to retract the tubular member proximally, and wherein a trigger and a lock of the retraction assembly are positioned such that that advancement of the plunger disengages the lock.

Belef teaches a device for sealing a puncture involving placement of a positioning tubular member within the puncture, retracting the tubular member, and then subsequently sealing the puncture by an occlusion member. Belef teaches a retraction assembly coupled to the tubular member **182** and the occlusion member **14**, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of a plunger **188** to thereby disengage the lock, the retraction assembly being spring biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged. The retraction assembly **180** comprises one or more connectors **192** that couple to the tubular member (Figures 1-3B, page 7, paragraph 81). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a retraction assembly which disengages a lock for the tubular member upon advancing the occlusion member or other actuator members that apply subsequent functions, as taught by Belef, to the device of Epstein since it was well known in the art that retraction mechanisms facilitate the operation of a device and reduce the number of steps applied. In addition, the retracted tubular member reduces

the profile of the device within the puncture site which increases visibility and facilitates sealing or occluding the puncture in subsequent steps.

3. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Epstein** (U.S. Patent No. **6,045,570**) in view of **Belef** (U.S. Pub. No. **2002/0193808**), as applied to claim 1 above, and further in view **Gershony** (U.S. Patent No. **5,626,601**).

Claims 2-5: Epstein and Belef disclose the claimed device, including the expandable device having a variable length dimension and an inner member slidably **33** coupled to an outer member **22** and comprising proximal and distal ends, the inner member distal end coupled to the expandable member **34** distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the proximal end of the expandable member when the expandable member is expanded and collapsed, respectively, and a housing **46** on the proximal end of the outer member (Figures 1-6, Epstein), except for an inflation lumen extending between the outer member proximal and distal ends, a piston slidably disposed within the chamber and coupled to the inner member, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen.

Gershony teaches a device for sealing a puncture comprising an inflation lumen **78** extending between proximal and distal ends of an outer member **86**, the proximal end of an expandable member **71** being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the

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inflation lumen, an inner member **73** slidably coupled to the outer member, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior, a housing **70** comprising a chamber in fluid communication with the inflation lumen, and an inflation port or reservoir chamber **77** which is connected to an inflation device to deliver fluid into the inflation lumen to expand the balloon (Figures 8-11, col. 6, line 33 to col. 7, line 7). Although Gershony does not expressly teach a piston, it was well known in the art that an inflation device comprises a plunger, piston or syringe activated by an actuator which may be connected to the inflation port **77**, as taught by Gershony. In addition, although the distal end and proximal ends of the expandable member **71** do not at least partially evert into the interior of the expandable member as the expandable member expands in Gershony, it would have been obvious to one of ordinary skill in the art to have proximal and distal ends of the expandable member evert into the interior of the expandable member since it was known in the art that everting ends maintain a seal against escaping fluid as well as strengthen the bond around the member onto which it is disposed. It would have been obvious to one of ordinary skill in the art at the time of invention to modify to Epstein and Belef by providing an inflatable expandable member or balloon, as taught by Gershony, since it was old and well known in the art for sealing devices to utilize balloons which occlude the puncture while minimizing trauma to tissue.

4. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Epstein** (U.S. Patent No. **6,045,570**) in view of **Belef** (U.S. Pub. No. **2002/0193808**), as applied to claim 7 above, and further in view of **Edwards** (U.S. Patent No. **6,562,059**).

Claim 8: Epstein and Belef disclose the claimed device, including tubular member further comprising a housing **46** on the proximal end thereof, the housing defining a cavity (Figure 1, Epstein), except for one or more connectors comprising a detent that collapses to allow the detent to be inserted into the cavity when the sheath is received in the tubular member lumen, the detent being biased to extend within the cavity and prevent the detent from being removed easily therefrom.

Edwards teaches a device for sealing a puncture comprising one or more connectors comprising a detent that collapses to allow the detent to be inserted into the cavity when the sheath is received in the tubular member lumen, the detent being biased to extend within the cavity and prevent the detent from being removed easily therefrom (col. 7, lines 22-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide one or more connectors comprising a detent, as taught by Edwards, to Epstein and Belef since it was known in the art that biased mechanisms prevent undesirable movement of the sheath relative to the tubular member although still movable when manipulated by the user.

Claims 9-10: Epstein and Belef disclose the claimed device including the housing comprising one or more side ports communicating with the delivery device (Figure 1, Epstein), except for the sheath comprising a lumen and an opening communicating with the lumen that is disposed within the cavity when the detent is inserted into the cavity,

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the sheath comprising a seal distal to the opening for engaging an inner surface of the tubular member to substantially seal the lumen of the tubular member, such that sealing compound delivered from the delivery device enters the one or more side ports and flows into the opening and through the lumen of the sheath.

Edwards teaches the sheath **52** comprising a lumen and an opening communicating with the lumen that is disposed within the cavity when the detent is inserted into the cavity, the sheath comprising a seal distal to the opening for engaging an inner surface of the tubular member **10** to substantially seal the lumen of the tubular member, such that sealing compound delivered from the delivery device enters the one or more side ports and flows into the opening and through the lumen of the sheath and a distal tip of the sheath extending beyond the distal end of the tubular member when the detent is inserted into the cavity, such that the sealing compound is delivered through the lumen of the sheath out the distal tip of the sheath and beyond the distal end of the tubular member (Figures 4C-4E and col. 6, line 48 to col. 7, line 38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sheath comprising a lumen and an opening and a seal, as taught by Edwards, to Epstein and Belef since it was known in the art that sealing the lumen while delivering the sealing compound would prevent undesirable leakage or flow within the device.

5. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Gershony** (U.S. Patent No. **5,626,601**).

Claims 21-23: Gershony discloses a device for sealing a puncture comprising an inflation lumen **78** extending between proximal and distal ends of an outer member **86**, the proximal end of an expandable member **71** having a variable length dimension and being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, an inner member **73** slidably coupled to the outer member that moves the expandable member towards and away from the proximal end of the expandable member, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior, a housing **70** comprising a chamber in fluid communication with the inflation lumen, and an inflation port or reservoir chamber **77** which is connected to an inflation device to deliver fluid into the inflation lumen to expand the balloon, and also an injectate port **79** for delivering a sealing compound into the puncture (Figures 8-11, col. 6, line 33 to col. 7, line 7). The outer member may be slidable through a tubular member or introducer sheath **61** (Figures 5-6). Although Gershony does not expressly teach a piston or plunger, it was well known in the art that an inflation device or delivery device comprises a plunger, piston or syringe activated by an actuator which may be connected to the inflation port **77** or injectate port **79**, as taught by Gershony.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Gershony** (U.S. Patent No. **5,626,601**) in view of **Belef** (U.S. Pub. No. **2002/0193808**).

Claim 24: Gershony discloses the claimed device except for a retraction assembly.

Belef teaches a device for sealing a puncture involving placement of a positioning tubular member within the puncture, retracting the tubular member, and then subsequently sealing the puncture by an occlusion member. Belef teaches a retraction assembly coupled to the tubular member **182** and the occlusion member **14**, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by advancement of a plunger **188** to thereby disengage the lock, the retraction assembly being spring biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged. The retraction assembly **180** comprises one or more connectors **192** that couple to the tubular member (Figures 1-3B, page 7, paragraph 81). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a retraction assembly which disengages a lock for the tubular member upon advancing the occlusion member or other actuator members that apply subsequent functions, as taught by Belef, to the device of Gershony since it was well known in the art that retraction mechanisms facilitate the operation of a device and reduce the number of steps applied. In addition, the retracted tubular member reduces the profile of the device within the puncture site which increases visibility and facilitates sealing or occluding the puncture in subsequent steps.

7. Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Epstein** (U.S. Patent No. **6,045,570**) in view of **Belef** (U.S. Pub. No. **2002/0193808**), as applied to claim 25 above, and further in view of **Cates** (U.S. Patent No. **6,162,240**).

Claims 26-27: Epstein and Belef disclose the claimed device, except for the retraction assembly comprising a stop.

Cates teaches a device for sealing a puncture including a retraction assembly comprising a stop **60** that limits proximal retraction of the tubular member relative to the occlusion member when the lock is disengaged and being disposed at a location such that proximal retraction of a tubular member corresponds substantially to a length of a puncture through tissue that is being sealed (Figures 1-2, 7-9 and col. 6, lines 46-60 and col. 7, lines 1-46). It would have been obvious to one of ordinary skill in the art to provide a retraction mechanism with a stop that limits proximal movement, as taught by Cates, to Epstein and Belef in order to selectively retract the tubular member after protecting and positioning the occlusion member prior to deployment, and therefore providing better user control.

Response to Arguments

8. Applicant's arguments with respect to claims 1-10 and 21-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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